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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,307	09/25/2003	Jay E. Birnbaum	131JB-001A	7258

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Bradley N. Ruben, PC
Suite 5A
463 First Street
Hoboken, NJ 07030

EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,307

Applicant(s)

BIRNBAUM, JAY E.

Examiner

Eric E. Silverman, PhD

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>NPL</u> |

DETAILED ACTION

Claims 1 – 15 are pending in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 reads “the method of claim 8”. A claim that reads to depend on itself is indefinite. Clarification is requested.

With regard to claim 13, the term “high pressure injection” is indefinite. A person of ordinary skill in the art would not know what pressures were “high”, since the term is not defined in instant specification or claims. Accordingly, it would be impossible for the artisan to ascertain the metes and bounds of the claim. Clarification is requested.

With regard to claim 14, the claim recites “the carrier is flowable is flowably forced”. It is unclear what is meant by this phrase. It is unclear what “flowably forced” means. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9 – 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Mailbach et al., US 6,846,837 B2.

Mailbach teaches a subungicide composition which comprises, in claimed embodiments, an antifungal agent, and an alpha-hydroxy acid (claims 1 – 3). In some embodiments, the composition is a non-soap semi-solid, such as a lotion, paste, medicated plaster, skin patch or gel (claims 13 – 21) Salicylic acid is the antifungal agent in one embodiment (claim 2). Note that since salicylic acid is an antifungal agent, an anti-inflammatory agent, and an alpha hydroxyl acid, and that instant claims require each of these ingredients to be present but do not require the ingredients to be different compounds.

Claims 1 – 5, 9, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bream et al., US 4,180,058.

Bream discloses a method of treating subungial fungal infections, particularly onychomycosis (abstract). The method comprises drilling holes in the nail, placing a keratolytic agent in the openings to enlarge the holes, and treating the condition through the holes with topical therapeutic agents, such as anti-fungal agents (abstract, drawings and descriptions thereof, claims 1 – 6). The carrier may be a solid or semi-solid, such as a wet dressing (claim 10) in certain embodiments. In another embodiment, the anti-

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fungal agent is an ointment that is a solution in petrolatum (col. 5, lines 37 – 52). The agent and carrier are placed onto the holes, and are the inherently drawn under the nail by capillary forces. Thus, the carrier is administered subungually between the nail plate and nail bed, meeting the limitations of claims 2 and 3. The capillary force injects the carrier with a pressure high enough so that it inherently reaches the nail bed, and this could be described as forcing the carrier between the plate and the nail bed, thus meeting the limitations of claims 13 and 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bream et al., US 4,180,058.

The teachings of Bream are discussed above.

Bream does not teach using an applicator to hold the ant-fungal agent and administer said agent.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use an applicator. The use of an applicator to deliver topical medicaments is well known in the art. The artisan would be motivated to use an applicator in order to conveniently apply the active agent to the desired location on the

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body, and to avoid contamination of the active agent. Since applicators are well known, the artisan would have a reasonable expectation of success of doing this. The expected result would be the use of an applicator in the method of Bream.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Bream or Mailbach, in either case in combination with American Academy of Dermatology disclosure "Internal Study Measures Quality of Life for Onychomycosis Patients, Sept. 22, 1999 (AAD).

The teachings of Bream and Mailbach are discussed above.

AAD teaches that pain is a common complaint among patients suffering from onychomycosis. AAD further teaches that the pain associated with this disease has been long under-estimated by many dermatologists and physicians.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to include an anesthetic in either the composition of Bream or that of Mailbach. The motivation to do so is to treat the pain that it associated with onychomycosis. Since anesthetics are well known in the art, the artisan would have a reasonable expectation of success. The expected result would be the compositions of Bream or Malbach with an added anesthetic.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Buck, US 6,231,840 B1.

No Claims are allowed. No claims are free of the prior art.

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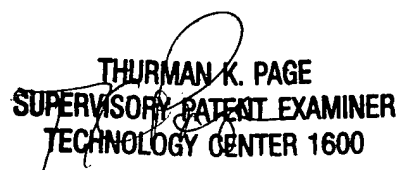
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD
Art Unit 1615



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600